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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,210	05/15/2001	David Radunsky	067062.0118	1568

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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 03/04/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,210

Applicant(s)

RADUNSKY ET AL.

Examiner

John Kim

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

1. Applicant's election of Group III (claims 12-20) in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants requested to cancel claims 1-11.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Oath claims the benefit of earlier priority to wrong U.S. provisional application no. 60/024,398 instead of U.S. provisional application no. 60/204,398 filed 5/16/00; furthermore, the oath does not claim the benefit to U.S. provisional application no. 60/230,106 filed 9/5/00.

New oath is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hemofilter having a nominal molecular weight cutoff greater than approximately 150,000 Daltons to sieve target molecules and target complex molecules from the blood stream and the nominal molecular weight cutoff less than approximately 1 million Daltons to avoid removal of significant amounts of immunoglobulins and similar larger molecules to prevent increasing the risk of opportunistic infection, does not reasonably provide enablement for hemofilter having an effective molecular cutoff less than approximately 5 million Daltons or 1 million Daltons which include an effective molecular cutoff of 0. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12-14 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is indefinite for failing to particularly point out whether the effective molecular weight cutoff is less than approximately 5 million Daltons. Claim 17 is indefinite for failing to particularly point out what are considered similar large molecules.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,571,418 (hereinafter referred to as Lee et al.) Lee et al teach an extracorporeal blood circuit comprising a blood circuit, a blood filter coupled to the blood circuit and having a membrane having an effective molecular cutoff of 100 - 150 kilo Daltons to remove target molecules in

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ultrafiltrate and filtered blood stream and inherent albumin replacement in the blood circuit in case of albumin loss (see col. 3, lines 40-47; col. 4, lines 40-54; col. 9, line 28 – col. 10, line 28).

9. Claims 12-16 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,193,681 (hereinafter referred to as Davidner et al.). Davidner et al teach an extracorporeal blood circuit comprising a blood circuit (151, 102, 107), a blood filter (106) coupled to the blood circuit and having a membrane having an effective molecular cutoff of 60 – 95 kilo Daltons to remove target molecules in ultrafiltrate and filtered blood stream (107) and a diluent source (13) including cleaned small molecules mixed with crystalloids infused into the blood circuit (see figure 1, col. 3, lines 9-27; col. 4, lines 27-34; col. 4, line 66 – col. 7, line 30).

10. Claims 12-15 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,919,369 (hereinafter referred to as Ash). Ash teaches an extracorporeal blood circuit comprising a blood circuit (24, 25, 30), a blood filter (30) coupled to the blood circuit and having a membrane having an effective molecular cutoff of 50,000 to 1 million Daltons to remove target molecules, target complex molecules i.e. protein-bound toxins and filtered blood stream (24) and a cleaned proteins (13) infused into the blood circuit via blood filter (30) (see figures 3A, 3B, 4; col. 5, lines 13-27; col. 6, line 66 – col. 7, line 24; col. 8, lines 39-44; col. 10, lines 18-42; col. 12, lines 30-52).

11. Claims 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,287,516 (hereinafter referred to as Matson et al.) Matson et al teach an extracorporeal blood circuit comprising a blood circuit (101, 103, 102, 105, 107), a blood filter (102) coupled to the blood circuit and having a membrane having an effective molecular cutoff of 100 - 150 kilo Daltons to remove target molecules in ultrafiltrate (112) and filtered blood stream (105) and a

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cleaned molecules in ultrafiltrate infused into the blood circuit (see figures 1A, 1B; col. 6, lines 10-67; col. 11, line 1 – col. 12, line 24).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

12. Claims 17-20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,618,343 and 5,744,042 and 6,497,675 and 5,855,782 teach related blood filtration.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.


When sending a draft amendment by fax, please mark the paper as “DRAFT”; otherwise, mark the paper “OFFICIAL”. This will expedite the processing of the paper.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
January 8, 2003